K053468

NESS

510(k) Summary:

JUL - 7 2006

NESS L300

Company Name:

NESS-Neuromuscular Electrical Stimulation Systems Ltd.

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Date prepared: May 5, 2006

Trade Name: NESS L300

Classification name: External functional neuromuscular stimulator

Class: II

Panel identification: Neurological devices

Product code: GZI and IPF

Regulation number: 882.5810

Predicate Devices: ODFS Dropped Foot Stimulator from Department of Medical Physics and Biomedical Engineering, Salisbury District Hospital, Salisbury, United Kingdom cleared under 510(k) no. **K050991** and **WalkAide**, NeuroMotion Inc in Edmonton, Alberta, Canada, cleared under 510(k) no. **K974514**

Device description:
The NESS L300 neuroprosthesis device consisting of a heel sensor, control unit (waist mounted or neck strap or in pocket) and below the knee orthosis containing electrodes and a controlled stimulation unit.

The heel sensor detects "heel off" and "heel contact" events during gait. It transmits signals to the stimulator, which initiates/ pauses the stimulation accordingly, thus activating the foot Dorsiflexors to ensure proper foot clearance during the swing phase, and proper foot placement during the stance phase.

The NESS L300 comprises of 4 main parts:
1. A lower leg **orthosis** with integrated stimulation unit (stimulator) and electrodes, RF communication and rechargeable battery.
2. A waist mounted (or in-pocket) **control unit** (CU), including a PDA interface, RF communication and AAA rechargeable battery.
3. **Foot sensor**, with RF communication and non-rechargeable coin battery.
4. **PDA** - HP iPAQ hx4700 Pocket PC. The PDA is intended to be used by the clinician for configuring the control unit with the functional parameters as appropriate for every patient.

Indications for Use:

The NESS L300 is intended to provide ankle dorsiflexion in individuals with drop foot following an upper motor neuron injury or disease. During the swing phase of gait, the NESS L300 electrically stimulates muscles in the affected leg to provide dorsiflexion of the foot; thus, it may improve the individual's gait. The NESS L300 may also facilitate muscle re-education, prevent/retard disuse atrophy, maintain or increase joint range of motion and increase local blood flow.

Substantial Equivalence:

The NESS L300 device has the same intended use and the same principle of operation as the **ODFS Dropped Foot Stimulator** from Department of Medical Physics and Biomedical Engineering, Salisbury District Hospital, Salisbury, United Kingdom cleared under 510(k) no. **K050991** and **WalkAide**, NeuroMotion Inc in Edmonton, Alberta, Canada, cleared under 510(k) no. **K974514**. The main technological difference between NESS L300 and the predicate devices is the RF wireless communication between the components versus the wired communication in the predicate devices. The NESS L300 was successfully tested for electromagnetic compatibility (EMC).

Conclusion:

The evaluation of the NESS L300 does not raise any additional concerns regarding safety and effectiveness and may therefore be considered substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 7 2006

NESS Neuromuscular Electrical Stimulation Systems
% Hogan and Hartson LLP
Mr. Jonathan S. Kahn
555 13th Street, N.W.
Washington, District of Columbia 20004-1109

Re: K053468
Trade/Device Name: NESS L300
Regulation Number: 21 CFR 882.5810
Regulation Name: External functional neuromuscular stimulator
Regulatory Class: Class II
Product Code: GZI
Dated: July 5, 2006
Received: July 5, 2006

Dear Mr. Kahn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson
Director,
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 4

Indications for Use

510(k) Number (if known): **K053468**

Device Name: NESS L300

Indications for Use:

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K053468